

In the Early Stage of Commercialization for their ForeCYTE Test designed to Identify High Risk Women having Atypical Ductal Hyperplasia Occurring in the Breast and their ArgusCTYTE Test for Breast Cancer Survivors, Atossa Genetics, Inc. is focused on Taking Measures to Prevent Breast Cancer

**Healthcare
Genetics**

Atossa Genetics, Inc.
1616 Eastlake Ave E, Suite 360
Seattle, WA 98102
800-351-3902
www.atossagenetics.com
www.nrlbh.com



Dr. Steven C. Quay
M.D., Ph.D., FCAP
Chairman, President & CEO

BIO:

Dr. Quay has served as Chief Executive Officer and Chairman since Atossa Genetics was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman, President and Chief Executive Officer of MDRNA, Inc. from August 2000 to May 2008 and as its Chief Scientific Officer until November 30,

2008. (MDRNA was previously known as Nastech Pharmaceutical Company and is currently known as Marina Biotech.) From December 2008 to April 2009, Dr. Quay was involved in acquiring Atossa's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at the Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the MASCT System. He oversaw the clinical testing and regulatory filing of the MASCT device with the FDA that led to its ultimate marketing clearance. Including the patents for the MASCT System, Dr. Quay has a total of 76 U.S. patents, 108 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the FDA. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics.

About Atossa Genetics, Inc. (Nasdaq: ATOS):

Atossa Genetics, Inc., The Breast Health Company™, is based in Seattle, Washington, and is focused on the prevention of breast cancer through the commercialization of diagnostic medical devices and patented, laboratory developed tests that can detect precursors to breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions.

**Interview conducted by:
Lynn Fosse, Senior Editor**

CEOCFO: Dr. Quay, what is the overall vision for Atossa Genetics?

Dr. Quay: Atossa Genetics is the breast health company. Our focus is on medical devices that are FDA cleared and laboratory tests that are run in our CLIA- certified laboratory, and on locally delivered therapeutics to treat the precursors to breast cancer. We believe that if we can identify the genetic and molecular changes that are going on in the ducts of the breast up to 10 years before a cancer appears, and then intervene in their progression from precursors of cancer-to-cancer, we can actually take measures to prevent breast cancer. As I like to say, we are not smart enough to cure cancer, but I think we can prevent it.

CEOCFO: What aspects of breast health are you looking at and what have you developed so far?

Dr. Quay: The Company's technology has been developed over a 14-year

period and more than \$50 million has been previously invested in research and development to get it to its current state. At about this time last year, we launched our first two tests. One is called the ForeCYTE Breast Health Test and the other is called the ArgusCYTE Breast Health Test. These are like the alpha and omega of breast health. The ForeCYTE test is designed to identify high risk women who are having either what is called "usual ductal hyperplasia" or "atypical ductal hyperplasia" occurring in the breast and to basically classify them as either at normal intermediate, or high risk of future breast cancer. Those terms are not ours. They were developed by the National Cancer Care Network, the American Cancer Society and other organizations. The terms have an actual quantification behind them. Normal risk means zero to 15 percent lifetime risk, intermediate risk means 15 to 20 percent, and high risk means above 20 percent risk for future breast cancer. The ForeCYTE test, which is simple and involves no radiation, can be done by a nurse in less than 15 minutes in the doctor's office. It includes three kinds of information that are put into a clinically validated algorithm to identify these risk categories. The three pieces of information are: family history, personal reproductive history, and what is actually going on in the left breast and the right breast at the time of the examination. It is the only test that brings those three pieces of critical clinical information together into one report that is actionable by doctors. If a woman is at normal risk, we want to see her again in a year and repeat the process. If she is at intermediate risk, we want to see her in six months. If she is at high risk we then want to go deeper into our understanding of what is going on in that particular patient by performing the FullCYTE Breast Health Test.

CEOCFO: What have you figured out that others have not, which allows you to put all of this together and provide an effective test?

Dr. Quay: We combined medical information that reaches all the way back 50 years, with genomic understanding from five years ago. What we have done is used the work done by the original visionary in cytopathology, Dr. George Papanicolaou, who invented the Pap smear for cervical cancer, the most successful test in the history of medicine. In 1953, he described the Pap smear. One year later, he took samples of spontaneous fluid coming from the nipple of women. About 5 percent of women show up at their doctor's with a little bit of fluid coming out when they are not lactating. Dr. Papanicolaou looked at the fluid under the microscope and said, "You know, this looks similar to what goes on in the cervix. There is a 10-year process involving cellular changes and I can identify each of the stages between normal and cancer." Our contribution is to have invented a device that provides that kind of spec-

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imen from every woman, and combine it with information from their medical and family history. That is what allows the ForeCYTE test to be done.

When I speak of using the advances of the last five years, I am speaking about our work where we have actually begun to sequence the full genome of the cells in these tiny samples of fluid, called Nipple Aspirate Fluid, or NAF, in order to really get at what the first genetic changes are that are going on in this hyperplasia process. To put this in prospective, the Pap smear, the name of the cervical cancer test developed by Dr. Papanicolaou, is the most successful screening test in the history of medicine because it lowered cervical cancer by 75 percent. It does that not by identifying cancer earlier but rather it identifies hyperplasia, which is the precursor to cancer. This allowed physicians in the

medical community to develop interventions in the hyperplasia process and prevent cervical cancer from forming. With the ForeCYTE test, Atossa Genetics now has the window into the breast to allow us to do the same thing.

The ArgusCYTE Test is at the other end of the spectrum in breast health, the omega if you will. This test is for the 2.9 million breast cancer survivors. These are women who have gone through what is called the "cut, burn and poison," the standard paradigm of surgery, radiation therapy and chemotherapy. Then every year on the anniversary of their diagnosis, they have a clinical exam to look for local recurrence in the breast that had the cancer and metastasis or distant recurrence, which means the cancer that may have spread to somewhere in the body. Right now, that latter test is rather crude. It involves a clinical exam and a questionnaire about whether you have pain in a particular spot, which is often the only test that we have for metastatic breast cancer in the initial evaluation. The ArgusCYTE test is a patented, FDA cleared blood test. It is like a liquid biopsy, as we call it, which identifies circulating

tumor cells up to 24 months before you actually get a clinical sign of metastasis in an organ. We take a blood sample and run it through an analysis to pull out the rare cancer cells. The cancer cells may be one out of 50 billion cells in that blood sample. We then interrogate those cells, if they are present, in order to determine which medication they would be sensitive to. We either tell the doctor the good news, that there are no circulating cells in their particular patient, or she does have circulating cells but we have also determined that they are sensitive, for example, to Roche's Herceptin® or some other drug, so please put her on Herceptin before she has any clinical symptoms or metastasis and re-test after that therapy. That is what we have been doing for a year and the doctors appreciate this tailored, personalized medicine approach in a new place where they

have never had an opportunity before. As we know, metastatic disease is typically what kills women, not the primary tumor. Once a tumor appears in a distant site in the body, the 5-year survival rate is under 15 percent. The ArgusCYTE test works at a point before the woman has clinical symptoms of metastasis and at a point when you can intervene. If a tiny amount of tumor is present somewhere in the body, by using these tailored therapies that are informed by the ArgusCYTE test you can actually prevent further metastasis.

CEOCFO: It does not sound like there is any downside to the test; is that correct?

Dr. Quay: As the CEO of this company and having been involved in the 14 years of development, I would agree with that statement. In the new cost-sensitive environment of medicine, we always have to balance cost and clinical benefit. Therefore, we are going to be adding new costs and we are going to figure out how this will fit into the new paradigm where medical practice is driven not only by what is best for the patient, but what is the most cost effective approach. In general, the costs of preventing a disease, especially one like breast cancer, far outweigh the costs of its treatment.

CEOCFO: Have investors and the portion of the medical community that should know about you and should pay attention become aware of Atossa Genetics?

Dr. Quay: We are at a very early stage of awareness in both the medical community and among investors. Until now we have focused on the medical and technical aspects of developing our technologies and our business and have been primarily inward facing. We are just now at an early stage in terms of the commercial launch of our tests and Atossa should be looked at as a ground-floor opportunity with significant upside potential for investors. Because we have had limited equity capital at this point in time, we have used it very judiciously. We have done what we have called a “soft launch” of about 40 doctors involved with the Fore-

CYTE test and less than 10 doctors involved with the ArgusCYTE test. The purpose is to provide the clinical utility to these doctors to be sure that the test operates in practice the way it did in the clinical trials that were used to support FDA clearance and to work out all the intricacies of a new company with medical devices that we sell to the doctors. Specimens are collected, they are sent to our specialized, Company-owned laboratory, the National Reference Laboratory for Breast Health, also in Seattle, and then detailed reports are provided to the doctors. There are many moving parts and over the last year we have worked out all of the kinks in this process. We are on the cusp of financing the national launch of the ForeCYTE and the ArgusCYTE tests in 2013, as well as two other tests that are in development and, most critically, what we call the Intraductal Treatment Program. When we find a woman who has one of her 14 ducts undergoing precancerous changes, we want to treat that hyperplasia through a tiny catheter that goes into the nipple in a painless fashion and then bathes the cells that are hyperplastic with a pharmaceutical agent that stops their growth and allows them to revert to normal.

CEOCFO: Is there much research competition in the specific areas you are looking at testing and the specific way that you are going about it?

Dr. Quay: No. At this point, the paradigm of breast health is to do nothing until you have cancer and then to cut it out, radiate it, and give the patient chemotherapy. The mammography machine manufacturers, the pharmaceutical companies, the surgeons, the radiation therapists, and the oncologists all participate in this current paradigm of finding cancer and then trying to treat it. For example, in the mammography space, the U.S. Preventive Services Task Force actually does not recommend mammography screening test for women under 50, even though we know that women in their twenties, thirties and forties have very high rates of breast cancer. This recommendation comes, in part, because the radiation from the mammogram actually produces breast cancer

at a small rate. While the rate of breast cancer exceeds the rate of cervical cancer by six- to almost 25-fold in women under the age of 40, we have no tests whatsoever for these women. Therefore, we are providing an absolutely new paradigm; much like was done decades ago in the cervix. It is going to be an educational process to change the mindset in order to actually provide the medical community with the tools to prevent breast cancer through these tests and subsequent treatments.

CEOCFO: Should you, or could you be going to the public or the various organizations that deal with breast cancer to get them involved?

Dr. Quay: It is very feasible, but I also have a very deliberate approach to that, as you might imagine. What I want to do is have my test, the ForeCYTE Breast Health Test, in the hands of doctors throughout the nation before promoting it widely. Therefore, I have quantified my goal. I would like 75 percent of the women in the U.S. to be within one hour of a doctor who is offering the Atossa Genetics ForeCYTE test. At that point in time, when we have begun to establish it nationwide, is exactly the timing when we would be pushing for more national exposure and education around our approach to breast health. Until that point in time, I think it could actually be counterproductive, if I could put it that way. That is because there is nothing worse than having a woman go to her doctor and say “I would like to try this new test” and the doctor has not read the extensive scientific and medical literature about all of the work that we have done or heard about how easy the test is to do in their office. That first encounter around it could be less than positive.

CEOCFO: Are there other tests that you will be working on in future?

Dr. Quay: Yes, there are two tests that we will be working on this year called the FullCYTE Test, which is the actionable test in high risk women identified by the ForeCYTE test, and what we call the NextCYTE Test, which is a test in women with cancer. I would like to go back and review a little bit of how cancer occurs, be-

cause this is not new science or new medicine, but it is a new focus using tools that actually deal with the biology. Each woman has two breasts and each breast has, on average, seven anatomic units of lobules and ducts. The lobules are responsible for making milk and the ducts are responsible for conducting milk to the nipple during breast feeding. If you can imagine then the average woman has fourteen of these units. Each unit is genetically distinct. They each came from one cell in the fetus during development. When a woman gets breast cancer, she does not actually get cancer of the entire breast or both breasts. In most cases she gets cancer of one unit in one breast. One of those 14 units undergoes hyperplasia and ultimately a cancerous change, a process we think takes about 10 years. When we remove a breast during surgery, we are actually taking out one diseased duct lobular unit and six normal units that are not undergoing any cancerous changes whatsoever. The ForeCYTE Test, as a reminder, identifies which breast, the left or the right, is undergoing precancerous changes. The FullCYTE test takes the examination one step further and identifies which of the seven duct / lobular units in the breast of concern is actually producing those changes. Therefore, there are up to seven catheters that are used in a painless fashion to collect a small sample down the ducts through the nipple and then each is analyzed in turn to identify which of the seven ducts is undergoing changes. As soon as we know which of those seven is undergoing the changes, we want to treat that duct and that duct only. In a clinical trial done at Johns Hopkins University in 17 women with cancer and published in October, the doctors were able to show that they could identify which duct has cancer and then could put chemotherapy right down the duct. In the study they showed they could actually treat the cancers and have no systemic side effects whatsoever, because the treatment stayed in the duct. That was just a pilot study but it shows the value of what the FullCYTE test and our Intraductal Treatment Program will be delivering in the future.

The other test is called the NextCYTE Test. The current standard of care when a woman has breast cancer is to have a surgeon remove the tissue. Some of that tumor is examined genomically for changes that are predictive of which therapy should be used. There is an established test that is being done in about a quarter of all women called the Oncotype DX Test and it interrogates 16 genes from the tumor to predict what therapy should be done. It was developed almost 10 years ago and used the latest technology at the time, but of course genomic technology has advanced very rapidly since then. The NextCYTE test that we have licensed from a European academic involves interrogating all 22,000 genes. That is as many genes as we have. We look at every single one of them and use an algorithm to determine which therapy is better. Therefore, you would expect when you test the entire set of expressed genes, the bigger data set would be superior and in a head to head clinical trial and it was. The NextCYTE test will be offered sometime next year to patients who have existing cancers, and that is about 235,000 women each year in the U.S.

CEO CFO: How do you deal, personally and as a company with the frustration of knowing that you have something that has such potential good and yet it is such an arduous process to get into widespread use?

Dr. Quay: You just get up every day, seven days a week. You put your head down, and you do your work and when you cannot do anymore work you go to bed, sleep, and do it again the next day. We lose one woman every minute from breast cancer and that is the driving force of everyone at this company. I feel privileged to work with the folks we have here. We have a great team and we are all just pulling 24/7 to get this technology out there as quickly as we can.

CEO CFO: Why should investors and people in the business community be paying attention today?

Dr. Quay: Because we are in a very important area of medicine and it is absolutely critical for the health of the entire community that these products

become standard of care. We are also a business, so let us talk numbers. If we look at each of our tests in order, the ForeCYTE test should be done in all women 18 to 73, about 110 million women in the US. Our test is \$500 on average at the Medicare reimbursement rates and therefore that is a greater than \$50 billion market. The FullCYTE test should be used in all of the approximately 10 percent of women who end up having hyperplasia; that is about 10 million women and that is about a \$3,000+ test. That is about a \$40 billion market. The NextCYTE test is intended for the 235,000 women who have breast cancer. That is also a very large market. The ArgusCYTE test was launched at about \$1,500, and is appropriate for the 2.9 million women who have existing breast cancer and are survivors. That is also a multi-billion dollar market. The therapeutics would be used in all of the atypical ductal hyperplasia patients, the final stage before women develop invasive cancer, about 66,000 each year, but it could be used in up the millions of women with hyperplasia, if it is as safe and effective as we believe it could be.

In summary, we have four diagnostics and a therapeutic which are each multiple billion-dollar opportunities and which together change the paradigm of breast health. To protect this business, we have put together a strong patent estate comprising 179 issued patents and 50 pending applications. An investor gets all of this right now for a \$60 million market cap. Our peers are diagnostic companies like Genomic Health (NASDAQ: GHDX) and Myriad Genetics (NASDAQ: MYGN) with market caps of \$860 million and \$2.6 billion, respectively. Roche (OTC: RHHBY), at \$172 billion, is a company that looks at medicine the same way we do, from the perspective of high tech diagnostics that work together with cutting edge therapeutics. Therefore, there is a lot of upside potential for investors in our stock who would like to participate in what we think will be a revolution in breast health.